UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,421	11/28/2000	Steven K. Yoshinaga	A-579D	4100

7590 01/03/2003

M PAUL BAKER ESQ
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP
1300 I STREET NW
WASHINGTON, DC 20005-3315

EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/03/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/728,421	YOSHINAGA, STEVEN K.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1 and 8-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 10/7/02 (Paper No. 15), is acknowledged.
Claims 1-31 *are pending.*

2. Applicant's election of Group II (claims 2-7) with a species election of SEQ ID NOS: 12 and 17 (encoded by SEQ ID NOS:11 and 16) in Paper No. 21 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1 and 8-31are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Although the instant claims are anticipated as set forth below, in the interest of compact prosecution, the search has been extended to include SEQ ID NO:6 (encoding SEQ ID NO:7).

Claims 2-7 *are under consideration in the instant application.*

Sequence Compliance

3. Sequence compliance: Applicant's provision of a corrected CRF, Sequence Listing, and Statement that the contents are identical on 10/28/02 (Paper No. 21), is acknowledged. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Drawings

4. The formal drawings submitted 10/28/02 have been approved by the Draftsman.

5. Applicant is reminded to amend the Brief Description of the Drawings to reflect the numbering used in the Figures and to describe each individual panel.

For example, "Figure 1" should read -- Figures 1A.1-1B --.

In addition, the description of the panel "B" for Figure 1, as amended in Paper No. 11, received 5/17/02, does not describe the material of panel "B" other than to indicate "B) (SEQ ID NOS:3, 4 & 5)..."

Appropriate correction is required.

IDS

6. It is noted that no IDS appears to have been filed in the instant application.

Specification

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

In addition, Applicant should avoid the use of "novel" in the title, as patents are presumed to be novel and unobvious.

It is suggested that Applicant amend the title to read -- B7-RP1 NUCLEIC ACIDS --.

8. The abstract is objected for failure to clearly include the elected invention. A new abstract is required which includes the subject matter claimed. In addition, Applicant should avoid the use of "novel" in the abstract.

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

10. The amendment filed 10/28/02 (Paper No. 21), is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

> the subject matter disclosing the disruption of the CRP1 gene in mice, and the sequence listing with respect to SEQ ID NOS:38 and 39.

Applicant is required to cancel the new matter in the reply to this Office action or point to support.

It is noted that in the amendment filed 10/28/02 the reference to page and line numbering did not correspond to the instant specification, USSN 09/728,421 (Applicant's docket number A-579D, renumbered in latter correspondence as 6843.0050-03000). With the exception of the subject matter noted supra, there was a clear textual correspondence which permitted entry of the replacement paragraphs. However, *Applicant is requested to ensure that the amendment filed 10/28/02 was in fact for USSN 09/728,421.*

Applicant is reminded to amend the Sequence Listing and to provide a new CRF and Statement if SEQ ID NOS:38 and 39 are not supported in the instant disclosure.

Claim Objections

11. Claim 3 is objected to as being dependent on a non-elected claim, claim 1. A claim which depends from a non-elected claim should be re-written as an independent claim, or to depend from an elected claim. Appropriate correction is required.

12. Claim 2 is objected to for the following informalities: in section (c) of claim 2, SEQ ID NO:6 is associated with Figure 12A, whereas SEQ ID NO:16 appears to be the appropriate nucleic acid (or alternatively, SEQ ID NO:17 the appropriate polypeptide sequence). Appropriate correction is required.

Claim Rejections - 35 USC § 112 second paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112.

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

14. Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 2 in sections (b) and (c) recites nucleotide sequences encoding polypeptides as set forth in a Figure, and then parenthetically references a SEQ ID NO. However, the SEQ ID NO is for a nucleic acid sequence, not the polypeptide sequence. Therefore, the claims are ambiguous as to whether the nucleotide sequence is limited to the SEQ ID NO, or whether the claim section is drawn to any nucleotide sequence encoding a particular polypeptide.

For examination purposes, the claims will be interpreted as reciting any nucleotide sequence encoding a particular polypeptide. Applicant should provide claim language that clearly sets for the metes and bounds of the claims.

B) The recitation of "hybridizes under stringent conditions" in claim 2(h) is ambiguous. Although the specification discloses on pages 24-26 general parameters for calculating high and moderate stringency conditions, the instant claims do not set forth the metes and bounds of "hybridizes under stringent conditions". Thus it is unclear which conditions are actually claimed.

It is suggested that Applicant amend the claims to recite a particular set of hybridization and wash conditions, such as those exemplified on page 24 of the specification, to overcome this rejection.

C) Claims 5-7 each recite "the host cell of claim 3". However, claim 3 recites a nucleic acid, not a host cell; therefore there is a lack of antecedent basis for the "host cell" of claims 5-7. It appears claims 5-7 should depend from claim 4, rather than claim 3.

D) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The specification discloses the nucleic acids of SEQ ID NO:11 and SEQ ID NO:16, encoding the polypeptides of SEQ ID NO:12 and SEQ ID NO:17 which are two forms of a human B7-RP1 polypeptide. The specification also discloses SEQ ID NO:6 encoding the polypeptide of SEQ ID NO:7 which is a mouse B7-RP1 polypeptide.

The claims recite:

A) nucleotide sequences encoding "percent identity variants" of a B7_RP1 polypeptide (claim 2c);
B) nucleotide sequences "comprising a fragment", and nucleotide sequences encoding a polypeptide "fragment";
C) "allelic variants" and "alternative splice variants"; and
D) a nucleotide sequence which "hybridizes under stringent conditions".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for the following reasons:

A) "Percent Identity Variants":

The claims recite a genus of nucleotide sequence encoding polypeptides having at least about 70% identity to a reference sequence, but do not require that the encoded polypeptides share any testable functional activity, a feature deemed essential to the instant invention. Applicant has disclosed nucleic acids encoding two human and one mouse B7-RP1 polypeptide, and thus has disclosed only a limited number of "variants". In the absence of a particular testable function and some structural basis for that function that must be maintained by the members of the genus, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See Regents of the University of California v. Eli Lilly & Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

B) "Fragments":

Fragment language that encompasses open (comprising) claim language permits unidentified flanking sequence to be added to the recited subsequence of a particular SEQ ID NO and so does not allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Fragments which comprise unidentified flanking sequence or have variation within their sequence thus do not meet the written description requirement. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (id at 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (id at 1116.).

C) "Allelic Variants" and "Splice Variants":

The term "allelic variants" encompasses any gene that occurs at essentially the same locus in the genome as the reference gene, as disclosed in the specification as-filed on page 23, lines 30-33. Similarly, a "splice variant" is a reference to an alternate form of a nucleic acid created by alternate processing of intronic sequence (e.g., specification, bridging paragraph of pages 23 and 24). However, there is insufficient written description in the specification of allelic and splice variants of the instant B7-RP1 encoding nucleic acids. Although the specification does provide alternate forms of human B7-RP1 polypeptides that may be encoded by different splice variants (SEQ ID NOS:11 and 16), there does not appear to be any description of the alternately processed transcripts. Neither does there appear to be adequate description of the locus to show that Applicant was in possession of 'allelic variants". Further, it is noted that allelic variants do not necessarily encode proteins having the same function. For example, Voet et al. (In Biochemistry. John Wiley & Sons. 1990, Vol.1, pages 126-128, and page 230) teaches that allelic variation in the β subunit of hemoglobin results in drastically different functions, even though the proteins share a high level of sequence and structural homology.

The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991). Thus the terms "allelic variant" and "splice variant" fail to provide a structure for which a function can be correlated, and in the absence of additional support in the specification as filed, these terms do not meet the written description provision of 35 U.S.C. 112, first paragraph.

D) "Hybridizes Under Stringent Conditions":

Applicant has disclosed and reduced to practice three nucleic acids encoding B7-RP1 polypeptides. The genus of nucleic acids which hybridizes to SEQ ID NOS:6, 11, 16, nucleic acids encoding "variants" (including allelic and splice variants) thereof, nucleic acid fragments thereof, is very large and a great deal of variability is encompassed by the instant claims. As noted supra the specification discloses only two human and one mouse nucleic acid. Thus the specification provides at most three members of the instant extensive genus since these nucleic acids would hybridize to their complements. In addition, the claims do not require that the hybridizing nucleic acids hybridize under any particular set of conditions. Finally, there is no requirement that the hybridizing nucleic acids encode polypeptides that share any particular function with the instant B7-RP1 polypeptides. Therefore the instant claims do not appear to provide an adequate written description of nucleotide sequences which "hybridize under stringent conditions".

The specification therefore fails to provide an adequate written description of the above noted claim limitations.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Alternatively, Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

17. Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

nucleic acids "consisting of" or "comprising" SEQ ID NO:6, 11 or 16;
nucleic acids encoding B7-RP1 polypeptides "consisting of" or "comprising" SEQ ID NO:7, 12 or 17;
nucleic acid fragments of SEQ ID NO:6, 11 or 16 in which the claim language clearly limits the fragments to *sub*sequence of SEQ ID NO:6, 11 or 16;
nucleic acids encoding polypeptides having only limited deviation from a reference sequence (e.g., a nucleic acid encoding a polypeptide 95% identical over the full length of SEQ ID NO:7) AND having a testable function supported in the specification as filed (and priority documents);

does not reasonably provide enablement for

A) nucleic acids encoding more extensive "percent identity variants";
B) nucleic "fragments" in any form in which the flanking sequences are undefined;
C) "allelic variants" and "alternative splice variants"; and
D) a nucleotide sequence which "hybridizes under stringent conditions"

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification discloses that the nucleic acids of SEQ ID NO:11 and SEQ ID NO:16 encode the polypeptides of SEQ ID NO:12 and SEQ ID NO:17, respectively, which are two forms of a human B7-RP1 polypeptide; and that the nucleic acid of SEQ ID NO:6 encode the mouse B7-RP1 polypeptide of SEQ ID NO:7. The specification also discloses in the Examples that B7-RP1 is, along with CRP1, part of a costimulatory receptor-ligand pair.

A) "Encoding Variant Polypeptides":

The state of the art at the time the invention was made recognized that even single amino acid differences can result in drastically altered functions between two proteins. For example, Metzler et al. (Nature Structural Biol. 1997; 4:527-531) showed that any of a variety of single amino acid changes can alter or abolish the ability of the CTLA4 to interact with its ligands CD80 and CD86 (B7-1 and B7-2) (e.g., summarized in Table 2). The variation in function among "B7-like" polypeptides is further emphasized by the teachings of Coyle et al. (Nature Immunol. 2:203-209 2001) who show that the B7-like family members have distinct expression patterns *and distinct functions* , even though they share certain conserved amino acid residues and domain structure (see in particular Figures 2 and 3). Given the extensive variation permitted by the instant claim language, the skilled artisan would not reasonably expect such "variant" polypeptides to have the same function as the instantly recited SEQ ID NOS, particularly when the family of B7-like proteins was known to have variable function.

It is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. The specification does not appear to provide sufficient guidance as to which residues should or should not be changed to preserve any particular function. Although the specification does provide working examples of nucleic acids encoding human and mouse B7-RP1 polypeptides, the variation permitted by the instant claim language is extensive. Consequently, the experimentation left to those skilled in the art to determine which nucleic acids encoding "variant" sequences would still encode polypeptides having the same function as a the human and mouse B7-RP1 polypeptides disclosed in the specification as filed is unnecessarily, and improperly, extensive and undue.

It is suggested that Applicant limit the claims to nucleic acids sequences encoding polypeptides having only limited variation (e.g. 95% identity) *over the full length* of the sequence, AND *possessing testable functional activity* supported in the specification and priority documents.

B) "Fragments":

The instant claims recite in various forms nucleic acids comprising "fragments" of a certain number of residues or encoding polypeptide fragments. "Comprising" and "encoding" language opens the claim up to the inclusion of additional residues of undisclosed identity and number flanking the recited "fragment". The skilled artisan can make fragments *limited* to *sub*sequences of the individual SEQ ID NOS without undue experimentation. However, before the skilled artisan can make nucleotide sequences with additional flanking sequence, guidance is required with respect to the identity of those flanking sequences. In the instant case however, the specification does not appear to provided this needed guidance. Therefore the scope of the instant claims does not appear to be commensurate with the enablement provided by the instant disclosure.

C) "Allelic Variants" and "Splice Variants":

The term "allelic variants" encompasses any gene that occurs at essentially the same locus in the genome as the reference gene, as disclosed in the specification as-filed on page 23, lines 30-33. Similarly, a "splice variant" is a reference to an alternate form of a nucleic acid created by alternate processing of intronic sequence (e.g., specification, bridging paragraph of pages 23 and 24). As noted supra, the specification does not appear to provide an adequate written description of "allelic variants" or "splice variants" of the instant sequences; thus the specification fails to provide sufficient guidance as to how to make these sequences.

In addition, neither allelic variants nor splice variants necessarily encode proteins having the same function. For example, Voet et al. (In Biochemistry. John Wiley & Sons. 1990, Vol.1, pages 126-128, and page 230) teaches that allelic variation in the β subunit of hemoglobin results in drastically different functions, even though the proteins share a high level of sequence and structural homology. Thus even had the specification clearly taught how to make allelic or splice variants of the instant sequences, the skilled artisan still would not know how to use the polypeptides encoded by them. Consequently, the scope of claims reciting either "allelic variants" or "splice variants" does not appear to be commensurate with guidance provided in the specification as filed.

D) "Hybridization":

The fact that two nucleic acid sequences will hybridize under moderate or stringent conditions does not in and of itself require that the two sequences encode proteins which share any functional activity. Thus the same observations apply to the recitation of "hybridizes" as were noted above with respect to "percent identity" language. Further, it was well know in the art at the time the invention was made that hybridization could occur between two sequence based upon short stretches of 100% identity. Thus a great deal of sequence variability *with respect to the full-length nucleic acid* is possible. Even when limited to a nucleotide sequence encoding a protein with 70% identity to a particular SEQ ID NO:, in the absence of a clear recitation that the identity is over the full length of the SEQ ID NO: the claim reads on sequence fragments. Finally, hybridization under conditions other than high stringency would be expected to permit a great deal of variation between the two hybridizing sequences, making it even more unpredictable that the two sequences would share the same function. Thus as for the recitation of percent identity, hybridization language in the absence of *a testable function* and limitations regarding both the hybridization *conditions* and the *sequence length* over which the hybridization takes place; does not allow the skilled artisan to make and use the hybridizing nucleic acids commensurate in scope with the instant claims without undue experimentation.

Thus with respect to the above noted claim limitations, each of which encompass considerable breadth and for each of which the specification provides only limited guidance; it would require undue experimentation of the skilled artisan to make and use such nucleotide sequences; thus the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claim Rejections – 35 U.S.C. §§ 102 and 103

18. It is noted that the instant claim language with respect to the nucleic acid of SEQ ID NO:6 encoding the polypeptide of SEQ ID NO:7 (322 amino acid form of mouse B7-RP1) and the nucleic acid of SEQ ID NO:11, encoding the polypeptide of SEQ ID NO:12 (288 amino acid form of human B7-RP1) appears to supported in parent USSN 09/244,448 (filed 2/3/99).

The instant claim language with respect to the nucleic acid of SEQ ID NO:16 encoding the polypeptide of SEQ ID NO:17 (302 amino acid form of human B7-RP1) does not appear to be supported in parent USSN 09/244,448 (filed 2/3/99), but does appear to be supported in parent USSN 09/264,527 (filed 3/8/99).

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 2-4 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Ishikawa et al. (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999).

Ishikawa et al. teach KIAA0653, and that the sequence information for the cDNA of KIAA0653 is available under accession number AB014553 (see entire document, but especially Table 1, first column). Ishikawa et al. also teach that the protein product of KIAA0653 was produced by in vitro translation (see comments in Section 2.1 on page 169 regarding original screening method); therefore, the cDNA clone KIAA0653 must also have been operably linked to an expression control sequence and placed in a host cell.

Ishikawa et al. teach that the KIAA0653 has homology to CD80, the original member of the B7 family of co-stimulatory proteins (e.g. see Table 2, page 175).

KIAA0653 encompasses the entire nucleotide sequence set forth in SEQ ID NO:11. Thus KIAA0653 is an isolated nucleic acid comprising:

the nucleotide sequence as set forth in SEQ ID NO:11;

the nucleotide sequence encoding a polypeptide as set forth in Figure 3A (SEQ ID NO:11) from residues 1-288;

a nucleotide sequence encoding a polypeptide fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 12;

a nucleotide sequence comprising a fragment of at least about 10, 15, 20, 25, 50, 75, 100 or greater than 100 nucleotides of SEQ ID NO:11; and

a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:11.

KIAA0653 also encompasses the nucleic acid sequence as set forth in SEQ ID NO:16 from approximately nucleotide 209 to 1098. Thus KIAA0653 is also a nucleotide sequence encoding a polypeptide fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 16, and a nucleotide sequence comprising a fragment of at least about 10, 15, 20, 25, 50, 75, 100 or greater than 100 nucleotides of SEQ ID NO:16.

KIAA0653 is also a nucleic acid that is an allelic variant and/or splice variant of instant SEQ ID NOS:11 and 16.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations would be inherent properties of KIAA0653.

The reference teachings thus anticipate the instant claimed invention.

21. Claims 2, 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. R23544 (GI:778432, released 20 April 1995).

R23544 is an isolated nucleic acid sequence 365 nucleotides in length that is 100% identical to instant SEQ ID NO:11 from nucleotide 407 to 771.

Instant SEQ ID NO:16 comprises instant SEQ ID NO:11; therefore R23544 is also 100% identical to instant SEQ ID NO:16 from approximately nucleotide 606 to 970.

R23544 is also taught to be a cDNA insert of a clone that is propagated in the lab host DH10B, a prokaryotic cell.

R23544 is also:

a nucleotide sequence encoding a polypeptide fragment of at least about 25, 50, 75, 100 or greater than 100 amino acid residues of instant SEQ ID NO: 12 or instant SEQ ID NO:17;

a nucleotide sequence comprising a fragment of at least about 10, 15, 20, 25, 50, 75, 100 or greater than 100 nucleotides of SEQ ID NO:11 or SEQ ID NO:16; and

a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:11 or SEQ ID NO:16.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations would be inherent properties of R23544.

The reference teachings thus anticipate the instant claimed invention.

22. Claims 2, 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. AA510455 (GI:2248309, released 08 July 1997).

AA510455 is an isolated nucleic acid sequence 440 nucleotides in length that is 99.7% identical to instant SEQ ID NO:6 from nucleotide 1 to 309, and 100% identical to SEQ ID NO:6 from nucleotide 120-309.

AA510455 is also taught to be a cDNA insert of a clone that is propagated in the lab host DH10B, a prokaryotic cell.

AA510455 is also:

a nucleotide sequence encoding a polypeptide fragment of at least about 25 or 50 amino acid residues of instant SEQ ID NO:7;

a nucleotide sequence comprising a fragment of at least about 10, 15, 20, 25, 50, 75, 100 or greater than 100 nucleotides of SEQ ID NO:6; and

a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:6.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The instant limitations would be inherent properties of R23544.

The reference teachings thus anticipate the instant claimed invention.

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al (DNA Res. June 1998; 5:169-176, see entire document) as evidenced by GenBank Accession No. AB014553 (released 06 Feb 1999) in view of Linsley et al. (U.S. Pat. No. 5,580,756).

The claims are drawn to a host cell comprising a B7RP-1 nucleic acid, wherein the host cell is a eukaryotic cell or a prokaryotic cell.

Ishikawa et al. have been discussed supra, and in brief, teach a B7 (CD80)-related polypeptide encoded by KIAA0653.

Although a host cell was necessarily present in the teachings of Ishikawa et al. since the protein was expressed, Ishikawa et al. do not explicitly teach either a eukaryotic host cell or a prokaryotic host cell comprising KIAA0653.

However, as noted supra, Ishikawa et al. do teach that the ordinary artisan at the time the invention was made was motivated to express the protein so that the protein could be further characterized.

Linsley et al. teach the B7 (CD80) polypeptide and its characterization as a co-stimulatory protein (see entire document, e.g., "Summary of the Invention" at columns 3-4).

Linsley et al. teach that the B7 protein could be expressed in either a prokaryotic or eukaryotic host cells (see columns 7-9 in particular).

The ordinary artisan at the time the invention was made would therefore have found it obvious to express the protein product of KIAA0653 in either a eukaryotic or prokaryotic host cell. The ordinary artisan at the time the invention was made would have been motivated to express the protein product of KIAA0653 using each type of host cell, since each system has its own advantages and disadvantages (e.g., glycosylation patterns, ease of isolation of protein, etc.). Expression of proteins in either eukaryotic or prokaryotic hosts was a matter of common practice at the time the invention was made, such that the ordinary artisan would have had a reasonable expectation that both types of host cells could be used. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

25. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

26. Claims 2-7 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-7 of copending Application No. USSN 09/728,420. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

27. No claim is allowed.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
January 2, 2003

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/2/03